

REMARKS

The Pending Claims:

Claims 45-64 are pending in the present application. Claims 47, 51, 52, 54-57, 59, 63, and 64 are withdrawn. Claims 45, 46, 48-50, 53, 58, and 60-62 are presently rejected. The rejected claims are directed to stents comprising, among other things, a wire having 1) at least one integrally-formed barb that 2) points in a predetermined direction at an angle relative to a longitudinal axis of the stent, where 3) the integral barb is unbent with respect to the wire and is free of weakening due to bending.

Decision By The Board of Patent Appeals and Interferences:

On October 14, 2009, the Board of Patent Appeals and Interferences ("the Board") reversed the Examiner's prior decision to reject the pending claims as anticipated by U.S. Patent No. 5,800,526 ("Anderson"). The Board found that "Anderson specifically teaches that the barbs 20 bend outwardly when the stent 10 expands radially." See Exhibit A; Board Appeal Decision at 5. In addition, the Board found that "the barbs 20 of Anderson are not necessarily unbent with respect to the stent wire." *Id.* Accordingly, the Board held that, "the Examiner erred in determining that the integral barbs of Anderson are unbent with respect to the stent wire." *Id.* at 6.

The Present Rejection:

Claims 45, 46, 48-50, 53, 58, and 60-62 are rejected as allegedly obvious under 35 U.S.C. 103 in view of Anderson and U.S. Patent Application Publication No. 2001/0027339 ("Boatman"). Neither Anderson nor Boatman, however, discloses, teaches, or suggests a stent, as presently claimed. Accordingly, this rejection is improper.

The Examiner never addresses the claimed feature that the integral barb points "in a predetermined direction" in the Office Action. With regard to the feature that the barb is "unbent with respect to the wire," the Examiner states that Anderson "appears to teach barbs unbent with respect to the stent struts." See Office Action; p. 3 (emphasis added). This is the very same argument that the Board already rejected. The Examiner's disregard of the Board's recent decision in this case is clear error. See

Exhibit A at 6 (“the Examiner erred in determining that the integral barbs of Anderson are unbent with respect to the stent wire.)

As the Board agreed, Anderson does not disclose, teach, or suggest a stent with each and every feature of the present claims. The Examiner has, moreover, failed to provide any support for the proposition that the present claims would have been obvious in view of Anderson, by itself. Accordingly, the Examiner has not established a *prima facie* case of obviousness over Anderson.

The Examiner asserts that the present claims would have been obvious in view of Anderson and Boatman. The Examiner does not contend that Boatman discloses a stent comprising a barb with any of the features recited in the present claims. And the Examiner never discusses or explains how Boatman would have motivated one of ordinary skill in the art to modify Anderson to provide a stent with these features.

Instead, the Examiner engages in a hindsight-driven “reverse-engineering” of the present claims. First, the Examiner cites paragraphs 24, 81, and 84 of Boatman for the proposition that stents may be designed to provide bending “over only certain curvilinear struts, while other sections of the stent do not deform.” See Office Action at 3. He then concludes, without any support, that it would have been obvious to one of ordinary skill in the art to “remove[] material only along the thicker curvilinear struts 12 [of Anderson] such that the arches 18 bend outwardly to direct the barbs 20 to face outwardly (as shown in figure 7 of Anderson).” See Office Action at 4 (emphasis added).

The Examiner has absolutely no basis for this assumption and, indeed, the teachings of Anderson and Boatman appear to the contrary. In particular, paragraph 84 of Boatman, which the Examiner cites, discloses that prior art stents “plastically deform at points of stress,” whereas what Boatman describes is “distribution of the lateral bending forces over the curvilinear struts of the present invention.” See Boatman; ¶84. Thus, contrary to the Examiner’s assertion, paragraph 84 appears to teach away from the Examiner’s proposal to provide points of stress in the Anderson stent by selectively removing material from some portions of Anderson’s cylindrical rings 12, but not others.

Moreover, the Examiner’s conclusion that one of ordinary skill would have removed material only along the thicker curvilinear struts suggests that the Examiner believes that the skilled artisan would not have removed material in the area of the

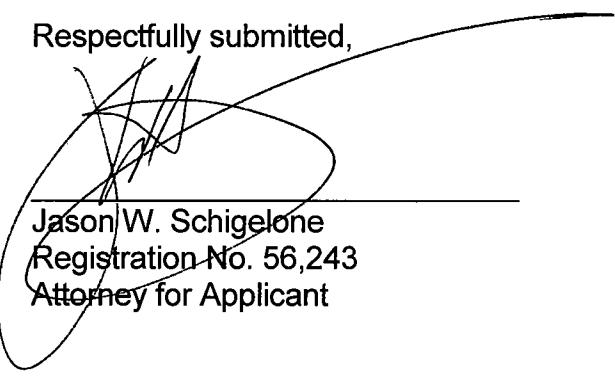
barbs 20. This directly contradicts Anderson's express teaching of step etching "in the areas of the attachment elements or barbs 20 . . . so that the barbs will bend outwardly when the stent is expanded." See Anderson; col. 9, lines 16-22; Office Action p. 3 (the Examiner recognizes that "Anderson further teaches stent material is removed at selective locations near the barbs to yield desired bending of the stent . . .") (emphasis added). Again, the Examiner ignores the Board's findings in this case. See Exhibit A at 4 ("Anderson further teaches using 'step etching' in the area of barbs 20 so as to, . . . remove portions of the material so that *the barbs will bend outwardly* when the stent is expanded.") (emphasis in original).

Neither Anderson nor Boatman, alone or in combination, discloses, teaches, or suggests a stent with each and every feature recited in the present claims. The Examiner has failed to establish a *prima facie* case of obviousness and, therefore, the present rejection is improper.

SUMMARY

Applicant believes that claims 45, 46, 48-50, 53, 58, and 60-62 are patentable and that the application is in a condition for allowance. Applicant respectfully requests that the Examiner withdraw the current rejection and allow the claims to issue. The Examiner is invited to contact the undersigned attorney via telephone if such communication would expedite this application.

Respectfully submitted,



Jason W. Schigelone
Registration No. 56,243
Attorney for Applicant

BRINKS HOFER GILSON & LIONE
P.O. BOX 10395
CHICAGO, ILLINOIS 60610

(312) 321-4200

EXHIBIT A



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BRINKS HOFER GILSON & LIONE			MATTHEWS, WILLIAM H	
P.O. BOX 10395				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte THOMAS A. OSBORNE and JASON A. MEAD

Appeal 2009-002753
Application 10/642,513
Technology Center 3700

Decided: October 14, 2009

Before WILLIAM F. PATE, III, MICHAEL W. O'NEILL, and
STEFAN STAICOVICI, *Administrative Patent Judges*.

STAICOVICI, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Thomas A. Osborne et al. (Appellants) appeal under 35 U.S.C. § 134 from the Examiner's decision rejecting claims 45, 46, 48-50, 53, 58, and 60-62. Claims 47, 51, 52, 54-57, 59, 63, and 64 have been withdrawn and claims 1-44 have been cancelled. We have jurisdiction over this appeal under 35 U.S.C. § 6 (2002).

THE INVENTION

The Appellants' invention relates to a stent with barbs 314 integral with the stent wire 322, where the barbs are not attached to the stent wire during manufacturing. Spec. 1, ¶ [0005]. That is, the barbs 314 are cut into the stent wire 322 and the wire is bent into a suitable stent wire shape such as to orient the barbs in a desired direction in relation to the longitudinal axis of the final stent shape. Spec. 59, ¶ [0198]; Spec. 61, ¶¶ [0204] and [0205]; and figs. 85 and 86a.

Claim 45 is representative of the claimed invention and reads as follows:

45. A barbed stent for deployment within the body of a patient, comprising:

a wire having at least one integrally formed barb that has not been attached to the wire during the manufacturing process, configured to engage tissue adjacent the stent;

wherein the wire comprises at least one bend connecting to at least two struts such that the at least one barb points in a predetermined direction at an angle relative to a longitudinal axis of the stent, wherein the at least one barb is unbent with respect to the wire and is free of weakening due to bending.

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THE REJECTIONS

The Examiner relies upon the following as evidence of unpatentability:

Anderson US 5,800,526 Sep. 1, 1998

Appellants seek review of the Examiner's rejection of claims 45, 46, 48-50, 53, 58, and 60-62 under 35 U.S.C. § 102(b) as anticipated by Anderson.

THE ISSUE

Have Appellants shown that the Examiner erred in finding that the barbs of Anderson are unbent with respect to the stent wire? The issue turns on whether the barbs of Anderson are “necessarily” unbent with respect to the stent wire.

SUMMARY OF DECISION

We REVERSE.

PRINCIPLES OF LAW

Anticipation

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros, Inc.. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631 (Fed. Cir. 1987).

Inherency

Under principles of inherency, when a reference is silent about an asserted inherent characteristic, it must be clear that the missing descriptive

matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991).

OPINION

Appellants argue that Anderson fails to teach a stent having unbent integral barbs. App. Br. 12. *See also* Reply Br. 2, 3. In response, the Examiner notes that the stent and barbs of Anderson:

. . . are machined from a flat sheet of metal (by laser cutting or chemical etching) such that the barbs will be directed outwardly upon expansion of the stent due to removed material in the area of the barbs (see col. 9 lines 16-26 and 42-50).

Ans. 3. Further, the Examiner points to Figures 4-7 of Anderson to show that because both wire bends 18 and barbs 20 face outwardly, the barbs 20 are not bent with respect to the wire. *Id.* In other words, the Examiner appears to take the position that because material has been removed in areas of the barbs 20, during expansion of stent 10 the wire 18 will bend at these regions such that barbs 20 will be oriented outwardly but will not bend with respect to the stent wire. We disagree with the Examiner's position for the following reasons.

It is our finding that Anderson teaches a stent 10 having a plurality of integral formed barbs 20. Anderson, col. 6, ll. 41-42 and 61-66; and fig. 1. Anderson further teaches using "step etching" in the area of barbs 20 so as to,

. . . remove portions of material so that *the barbs will bend outwardly* when the stent is expanded. In other words, step etching allows for the removal of material in highly selective areas so that upon

radial expansion of the stent, areas having less material will have a tendency to bend or distort, such as with *the barbs bending outwardly* to engage the aortic valve.

Anderson, col. 9, ll. 16-26 (emphasis added).

Hence, Anderson specifically teaches that the barbs 20 bend outwardly when the stent 10 expands radially. However, having the barbs bent outwardly does not mean that the barbs themselves are bent with respect to the wire 18, as Appellants suggest. Likewise, it does not mean that it is the wire 18 that undergoes bending and not the barbs 20, as the Examiner proposes. Hence, in a first instance, we find that both situations are equally probable.

However, inherency may not be established by probabilities or possibilities.

In re Oelrich, 666 F.2d 578, 581 (CCPA 1981) (quoting *Hansgirg v. Kemmer*, 102 F.2d 212, 214 (CCPA 1939)). In this case, Anderson also teaches uniform radial expansion of the stent 10 without substantial out-of-plane twisting. Anderson, col. 8, ll. 17-19. Accordingly, if the wire 18 undergoes bending to orient the barbs 20 outwardly, as the Examiner suggests, then the stent 10 will also likely undergo out-of-plane twisting, which is in contrast to Anderson's specific teachings. As such, we agree with Appellants that the barbs 20 of Anderson are not necessarily unbent with respect to the stent wire. *See Reply Br. 3.*

In conclusion, we find that the Examiner has not provided sufficient evidence to support the finding that the barbs 20 of Anderson are necessarily unbent with respect to the stent wire. Accordingly, the rejection of claims 45, 46, 48-50, 53, 58, and 60-62 under 35 U.S.C. § 102(b) as anticipated by Anderson cannot be sustained.

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CONCLUSION

Appellants have shown that the Examiner erred in determining that the integral barbs of Anderson are unbent with respect to the stent wire.

DECISION

The Examiner's decision to reject claims 45, 46, 48-50, 53, 58, and 60-62 under 35 U.S.C. § 102(b) as anticipated by Anderson is reversed.

REVERSED

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BRINKS HOFER GILSON & LIONE
P.O. BOX 10395
CHICAGO, IL 60610